

CURRENT LISTING OF CLAIMS WITH MARKINGS
TO SHOW CHANGES MADE:

1. (Original) A pharmaceutical kit for nasal drug delivery comprising:
an aqueous solution of cyanocobalamin and excipients in a container and;
a droplet-generating actuator attached to said container and fluidly connected to the cyanocobalamin solution in the container; wherein said actuator produces a spray of the cyanocobalamin solution through a tip of the actuator when said actuator is engaged, wherein said spray of cyanocobalamin solution has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.
2. (Original) The kit of claim 1 wherein said spray comprises droplets wherein less than 5% of said droplets are less than 10 µm in size.
3. (Currently Amended) The kit of claim 1 wherein ~~in~~ the aqueous solution of cyanocobalamin has a viscosity of less than 1000 cPs, and wherein ~~said solution of cyanocobalamin has a bioavailability of cyanocobalamin of about 7% relative to an intramuscular injection of cyanocobalamin,~~ with the proviso that mercury and mercury containing compounds are not present in the solution.
4. (Original) The kit of claim 3 wherein the spray is comprised of droplets of the cyanocobalamin solution wherein less than 5% of the droplets are less than 10 µm in size.
5. (Original) The kit of claim 3 wherein the spray has a spray pattern major axis and minor axis of between 25 and 40 mm each.
6. (Original) The kit of claim 3 wherein the solution of cyanocobalamin is further comprised of citric acid and sodium citrate wherein the solution has a pH of from about 4-6.
7. (Original) The kit of claim 6 wherein the pH of the solution is about 5.
8. (Original) The kit of claim 3 wherein cyanocobalamin is present in solution at a concentration of between 0.5-1 % by weight.
9. (Original) The kit of claim 8 wherein the concentration of cyanocobalamin in solution is about- 0.5%.

10. (Original) The kit of claim 6 wherein the citric acid is present in solution at a concentration of about 0.12%, and the sodium citrate is present in solution at a concentration of about

0.32%, in water.

11. (Original) The kit of claim 3 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution wherein 50% of the droplets are 26.9 μm or less in size.

12. (Original) The kit of claim 3 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution, wherein 90% of the droplets are 55.3 μm or less in size.

13. (Previously Presented) The kit of claim 3 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5 μm or less in size.

14. (Currently Amended) A kit for administering intranasally a cyanocobalamin solution comprised of a container, a solution of cyanocobalamin in the container, and an actuator attached to said container, wherein a spray of cyanocobalamin solution is expelled through a tip of said actuator when said actuator is engaged wherein said aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, and has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the solution of cyanocobalamin contains no mercury or mercury-containing compounds, and wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.

15. (Original) The kit of claim 14 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution, wherein less than 5 % of the droplets of the cyanocobalamin spray are less than 10 μm in size.

16. (Previously Presented) The kit of claim 14 wherein the cyanocobalamin spray is comprised of droplets of the cyanocobalamin solution, and wherein 50% of the droplets of the cyanocobalamin spray are 26.9 μm or less in size.
17. (Previously Presented) The kit of claim 14 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3 μm or less in size.
18. (Previously Presented) The kit of claim 14 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5 μm or less in size.
19. (Previously Presented) The kit of claim 14 wherein the spray has a spray pattern major axis of about 35.3 mm and a minor axis of about 30.8 mm.
20. (Currently Amended) A method for administering cyanocobalamin intranasally comprised of providing an aqueous solution of cyanocobalamin, wherein the solution of cyanocobalamin has a viscosity of less than 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin of about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that mercury and mercury containing compounds are not present in the solution, wherein the cyanocobalamin formulation is administered into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.
21. (Previously Presented) The method of claim 20 wherein the spray produces droplets, wherein less than 5% of the droplets are less than 10 μm in size.
22. (Previously Presented) The method of claim 20 wherein the spray has a spray pattern major axis and minor axis of between 25 and 40 mm each.
23. (Previously Presented) The method of claim 20 wherein the solution of cyanocobalamin is further comprised of citric acid and sodium citrate wherein the solution has a pH of from about 4-6.
24. (Previously Presented) The method of claim 23 wherein the pH of the solution is about 5.

25. (Previously Presented) The method of claim 20 wherein cyanocobalamin is present in solution at a concentration of between 0.5-1 % by weight.
26. (Previously Presented) The method of claim 20 wherein the concentration of cyanocobalamin in solution is about 0.5%.
27. (Previously Presented) The method of claim 20 wherein the citric acid is present in solution at a concentration of about 0.12%, and the sodium citrate is present in solution at a concentration of about 0.32%, in water.
28. (Previously Presented) The method of claim 20 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 50% of the droplets are 26.9 μm or less in size.
29. (Previously Presented) The method of claim 20 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3 μm or less in size.
30. (Previously Presented) The method of claim 20 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5 μm or less in size.
31. (Currently Amended) A method for administering cyanocobalamin comprised of providing an aqueous solution of cyanocobalamin wherein said aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, and has a viscosity less than about 1000 cPs, and wherein ~~said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the solution of cyanocobalamin contains no mercury or mercury-containing compounds, and wherein the cyanocobalamin solution is administered into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.~~

32. (Previously Presented) The method of claim 31 wherein the cyanocobalamin spray produces droplets of the solution, wherein less than 5 % of the droplets are less than 10 μm in size.
33. (Previously Presented) The method of claim 31 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 50% of the droplets are 26.9 μm or less in size.
34. (Previously Presented) The method of claim 31 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3 μm or less in size.
35. (Previously Presented) The method of claim 31 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5 μm or less in size.
36. (Previously Presented) The method of claim 31 wherein the spray has a spray pattern major axis and a minor axis of about 25 - 40 mm each.
37. (Currently Amended) A method for elevating the vitamin B12 levels in the cerebral spinal fluid (CSF) comprising administering intranasally a sufficient amount of a solution of cyanocobalamin so that the average ratio of vitamin B 12 in the CSF to that in the blood serum (E12 CSF/B12 Serum x 100) is increased to at least about 1.1, wherein said aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, and has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the cyanocobalamin solution contains no mercury or mercury-containing compounds and wherein the cyanocobalamin solution is administered into a nose of an individual through an actuator tip as a spray, wherein the spray has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.
38. (Previously Presented) The method of claim 37 wherein the cyanocobalamin spray produces droplets of the solution, wherein less than 5 % of the droplets are less than 10 μm in size.

39. (Previously Presented) The method of claim 37 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 50% of the droplets are 26.9 μm or less in size.
40. (Previously Presented) The method of claim 37 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 90% of the droplets are 55.3 μm or less in size.
41. (Previously Presented) The method of claim 37 wherein the cyanocobalamin spray produces droplets of the solution, and wherein 10% of the droplets are 12.5 μm or less in size.
42. (Previously Presented) The method of claim 37 wherein the spray has a spray pattern major axis and a minor axis of between 25 - 40 mm each.